DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

74017d

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 15, 2003 W/L 34-03

Mr. Dan V. Nguyen, President
Ocean Choice Seafood Company
506 Stanford Avenue
Los Angeles, CA 90013

Dear Mr. Nguyen:

On January 23 & 28, 2003, we inspected your seafood processing facility, located in Los Angeles, California. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly your ready-to-eat sashimi grade tuna are adulterated, in that the fresh fishes have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for fresh raw histamine forming fish lists a critical limit of "[redacted] that is not adequate to control histamine formation during transit to your firm. FDA recommends that for histamine forming fish that are more than four hours in refrigerated transit (such as your imported tuna are) that:

   All lots received are accompanied by transportation records that show that the fish were held at or below 40°F throughout transit. You may wish to consider the use

of time/temperature data loggers; recorder thermometers; or digital thermometers.

Or for fish held under ice or chemical cooling media: There is an adequate quantity of ice or other cooling media at the time of delivery to completely surround the product.

2. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However your firm could not provide any monitoring records for the monitoring of the safety of water; the condition and cleanliness of food contact surfaces; the prevention of cross-contamination from insanitary objects to food; the maintenance of hand washing and hand sanitizing facilities; the protection of food from chemical contaminants; the proper labeling and use of toxic compounds; the control of employee health conditions; and the exclusion of pests from for January, 2003 as well as all of 2001 and 2002.

3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor one or more of the eight areas of sanitation with sufficient frequency to ensure control as evidenced by:

   Failure to take necessary precautions to protect against contamination of food and food contact surfaces as evidenced by:

   - An employee was observed using a tool to unclog a processing room drain, then placing this tool immediately onto a processing room cutting board, which is used to fillet salmon and tuna.
   - A live fly was observed to land directly onto a piece of processed, sashimi-grade tuna.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility

to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your written reply should be directed to:

Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd, Suite 300
Irvine, CA 92612-2445.

If you have questions regarding any issue in this letter, please contact Mr. Robert B. McNab, Compliance Officer at (949) 798-7709.

Sincerely,

Alonza E. Cruse
District Director